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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

JOHANNSEN, DIANA B

ART UNIT PAPER NUMBER

1634

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/955,367

Applicant(s)

ATTIE ET AL.

Examiner

Diana B. Johannsen

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5 and 7-11 is/are pending in the application.
- 4a) Of the above claim(s) 4,7,9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,8 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 October 2005 has been entered, as have the complying sets of claim and specification amendments filed 17 January 2006.
2. Claims 1, 5, 8, and 11 have been amended and are now under consideration. Claims 4, 7, and 9-10 remain withdrawn (see below).
3. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is NON-FINAL.**
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restriction

5. It is again noted that claims 4, 7, and 9-10, and genes and combinations other than those elected (as noted in the prior Office action of April 8, 2004), are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the Response of April 11, 2003.

Claim Objections

6. Claim 1 is objected to because of the following informalities: it is again noted that the claim (which now includes multiple steps) recites “comprising the step of” rather than “comprising the steps of.” Appropriate correction is required.

Additionally, as claim 5 has been amended to add an additional step, it is suggested that the word “and” at the end of the “taking” step be deleted.

Claim Rejections - 35 USC § 112

7. Claims 1, 5, 8, and 11 are rejected under 35 U.S.C. 112, first paragraph, for reasons set forth in the Office action of April 8, 2004. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

As discussed in the Office action of April 8, 2004, it is unpredictable as to whether one of skill in the relevant art could use applicant’s invention in a manner reasonably commensurate with the claims. Because Applicant’s disclosure provides evidence that SREBP, cytochrome c oxidase subunit VIIa, and stearyl-CoA desaturase each exhibit decreased expression in adipose tissue of obese mice, one of skill in the art would reasonably consider decreased expression of these genes in adipose tissue as one factor useful in diagnosing obesity in mice. However, the specification does not include these genes among those disclosed in Table 3 as being associated with hyperglycemia and diabetic disease. It is further noted that the specification itself teaches that “only 10% of individuals who are obese are diabetic” (p. 2); accordingly, the teachings of the specification indicate that a gene exhibiting modified expression in

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an obese individual might or might not exhibit a similar pattern of expression in a diabetic. Further, the specification does not provide evidence that determining the expression of any of these genes would allow one to determine a diagnosis for diabetes susceptibility, prognosis for obesity, diagnosis or prognosis for incipient obesity, or "transition from obese" to diabetic in any type of individual, or a diagnosis of obesity in any individuals other than mice. Thus, the teachings of the specification alone are insufficient to enable the use of the claimed invention, with the exception of obesity diagnosis in mice. Lacking guidance from the specification, one of skill in the art may look to the teachings of the art for further guidance and enablement of a claimed invention. However, in the instant case, the prior art is silent with respect to an association between expression levels of SREBP, cytochrome c oxidase subunit VIIa, and stearyl-CoA desaturase and diabetes or diabetes susceptibility, as well as obesity and the transition from obesity to diabetes. Given the high level of skill of one skilled in the relevant art, it is clearly within the ability of such an artisan to carry out further experimentation aimed at identifying such associations. However, the outcome of such further research cannot be predicted, and thus it is unknown as to whether any quantity of experimentation would be sufficient to enable the claimed invention. Thus, it would require undue experimentation to use applicant's invention in a manner reasonably commensurate with the instant claims.

In response to the rejection, Applicants have merely reiterated their assertion that "the mouse model used in the data described in this patent application is a common accepted model to investigate insulin sensitivity and progression of diabetes." This

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argument has been thoroughly considered but is not persuasive. As discussed in the prior Office action of May 24, 2005, while Applicants' response includes statements that the mouse models employed in the specification are "commonly used" models for diabetes and diabetes progression, Applicants have not provided any evidence that this is the case, or cited any prior art references establishing, e.g., that data obtained using their models correlates with findings in humans. In order to establish a broader scope of enablement, it would be necessary to, e.g., provide actual evidence that gene expression in the models used correlates with gene expression in humans; mere statements that a model is "commonly used" are not evidence. Further, the fact that it is well known that insulin resistance is related to diabetes or progression to diabetes does not establish a relationship between decreased expression of a group of genes in obese mice and the levels of expression of those same genes in diabetic mice, diabetic humans, etc. It is again noted that the genes of the claims were not included in Table 3 of the specification (i.e., in the Table reciting genes associated with diabetic disease), and that the specification itself states that "only 10% of individuals who are obese are diabetic" (p. 2). Finally, while it may in fact be a "current belief in the art that a change in lipogenic capability in adipose tissues is indicative of a change to insulin resistance," it remains that Applicants have not provided evidence in any form that establishes an actual association between expression of the genes of the claims and diabetes susceptibility, prognosis, predisposition, etc. Thus, Applicants' arguments are not persuasive, and this rejection is maintained.

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8. Claims 1, 5, 8 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants' statement (at page 6 of the Remarks of both 24 October 2005 and 17 January 2006) that "It is believed that the changes to the claims" made by Applicants' amendment "fully and completely address" the rejections of record under this paragraph is noted. However, the claims remain indefinite for the reasons set forth below (which constitute both new rejections necessitated by Applicants' amendments and rejections already of record that were not fully addressed by Applicants' amendments).

Claim 1 is indefinite because it is unclear whether the claim requires the determination of the expression pattern of "any of the" three genes of the claim (as stated in the "determining" step), or whether one must determine the expression pattern of all of the genes, as suggested by the recitation in the "diagnosing" step that an individual is considered susceptible to diabetes if "the expression of all of these genes is decreased." It is not clear how the "determining" step as presently written relates to or would allow one to carry out the "diagnosing" step as written. Clarification is required.

Similarly, claim 5 is indefinite because it is unclear whether the claim requires the determination of the expression pattern of one of the three genes of the claim (as stated in the "determining" step), or whether one must determine the expression pattern of all of the genes, as suggested by the recitation in the "considering" step that an individual is considered predisposed to diabetes if "the expression pattern of all of the genes is decreased." It is not clear how the "determining" step as presently written relates to or

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would allow one to carry out the “considering” step as written. It is further noted that the term “considering” is vague and indefinite. The claim is drawn to a method “for the diagnosis of predisposition to diabetes,” and it is not clear whether the term “considering” constitutes a synonym for “diagnosing,” or whether this language is more broad, such that the claim might encompass, e.g., mere thought processes, as opposed to an actual step of “diagnosing.” Clarification is required.

Claim 8 remains indefinite over the recitation of the limitation “the decreased level of expression” because there is insufficient antecedent basis for this limitation in the claim.

Claim 11 is indefinite because it is unclear whether the claim requires the determination of the expression pattern of one of the three genes of the claim (as stated in the “determining” step), or whether one must determine the expression pattern of all of the genes, as suggested by the recitation “a decrease in expression of all of those genes....being associated with the transition from obese to diabetic.” Further, it is not clear how determining a “decrease in expression.... associated with the transition from obese to diabetic” relates to the preamble of the claim, which recites a method “for the diagnosis or prognosis of obesity, incipient obesity, or the transition from obese to diabetic.” It appears that the steps of the claim merely result in determination of a decrease “associated with the transition from obese to diabetic,” rather than achieving the objectives set forth in the claim preamble. Thus, clarification with regard to how the steps of the claim achieve the objective thereof is also required.

Conclusion

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Diana B. Johannsen
Primary Examiner
Art Unit 1634

2/2/2006